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In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, INC.

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INTRODUCTION

The National Association of Pharmaceutical Manufacturers, Inc. ("NAPM"), respectfully submits this *amicus curiae* brief in support of petitioners in the captioned matter. A letter of consent signed by all parties to this petition has been filed with the Clerk of the Court.

NAPM is a national trade association representing more than 100 manufacturers and distributors of prescription and "over-the-counter" pharmaceutical products throughout the United States. For many years, NAPM has been the leading national spokesperson for what is commonly known as the generic drug industry. NAPM has represented the industry in the courts both as a party and as an *amicus*. It has appeared before administrative tribunals. It has also appeared in hearings before Congress and the legislatures of numerous states. The petitioners herein, Inwood Laboratories, Inc. ("Inwood") and Premo Pharmaceutical Laboratories, Inc. ("Premo"), are members of NAPM.[1]

This brief discusses the wide-ranging impact that the decision below will have on both the generic drug industry and the public at large. As we shall show, that decision deals a decisive blow against competition and lower drug prices.

ARGUMENT

I.

THE DECISION BELOW IS CONTRARY TO A LONG-ACCEPTED, LEGAL AND NECESSARY INDUSTRY PRACTICE

Do the colors of a drug product remain forever the exclusive property of the patent holder after the patent expires? The Second Circuit says they do, and we assert that that is not, and should not be, the law.

We respectfully submit that what this case concerns is the right of generic drug manufacturers to effectively compete in the

1. The law firm of NAPM's General Counsel also represents Inwood.

market. The real issue presented in this controversy is dollars. Generic companies have proven that they can deliver equivalent products at a fraction of the "brand-name" companies' prices.

It is no accident that this case was filed by Ives on the eve of New York State's enactment of a generic drug substitution law. The efforts to stop such legislation — legislation which gave an imprimatur to the public interest in obtaining lower-priced generic drug products — failed. Other concerted efforts to thwart generic drug sales continue. We submit that this case is one of those efforts.

For the reasons set forth below, and for those contained in the brief of petitioner Inwood, we respectfully submit that the decision below conflicts with the public interest and the law. The decision contravenes an accepted and legal marketing practice which has existed from the inception of this industry. Its inevitable result is a further concentration of economic power in an already concentrated industry. Most importantly, the decision seriously impairs the generic industry's ability to deliver essential medications to fixed-income citizens and governmental agencies at an affordable cost.

A. The Functional Role of Color in the Manufacture and Sale of Pharmaceutical Products

The courts cannot be color-blind. Color is a force. It is a potent force to move people and to make people act. This may arise inherently from the color itself or it may be an acquired effect as a result of experience. A color may thus create a calm effect, a good reaction or a negative reaction. As an example of an acquired effect, we know that butter is identified as a yellow product. Most people would not pick up a stick of butter from a supermarket shelf if it looked green.

Color is a science. Extensive scientific research has been done in the field of color and its effect on man's behavior. It has been found, for example, that a pinkish color will have a tranquilizing effect to reduce agressive behavior and potential violence.[2] It is significant that, in contrast to all of the statements that choice of color is a random decision, the major drug companies are treating color as a science. One of the major pharmaceutical companies, Parke-Davis, conducted an extensive investigation into the use of color in pharmaceutical products.[3] It reported that:

> "[N]umerous investigations in the U.S., England and Continental Europe have established that patients show preferences — and aversions — to various colors. Often these reactions reflect the state of mind of the patients due to their particular ailments."

The importance of color in marketing is undisputed. Color is big business. Large sums of money are expended for color additives to be used in foods, drugs and cosmetics. Extensive market surveys are conducted, and companies spend a great deal of money and time in order to obtain approval from the Food and Drug Administration ("FDA") for such colors. All of this effort is expended for the purpose of finding the most effective marketing color for the specific product.

With a new understanding of the role of color, the major pharmaceutical companies have completely reversed their

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2. Schauss, "Tranquilizing Effect of Color Reduces Aggressive Behavior and Potential Violence", 8 *J. Orthomolecular Psychiatry* 218 (1979).

3. "Capsule Color Considerations" and "The Hard Gelatin Capsule - A Contribution to Drug Safety" (Parke-Davis Division of Warner-Lambert Co. 1980) [newsletter and accompanying advertising circular] [hereinafter referred to as "Parke-Davis Study"].

position in recent years. Years ago, these same companies requested that the government make color, size and shape required specifications for government bids. That request has been discarded. The large brand-name manufacturers are now trying to prevent the generic manufacturers from using the same colors for generic products.

The brand-name company has a period of seventeen years in which to use a specific color for its product. During that time, the product is the only one being marketed. Color over that seventeen-year period develops important functional attributes. Those attributes should not serve as the excuse for extending a seventeen-year patent into one in perpetuity.

Set forth below are several of the well-recognized functional attributes of color:

1. Patient Anxiety and Acceptance

It is a recognized fact that persons using prescription drugs are reluctant to accept products which bear a different appearance. This is particularly true in the case of patients who take drugs over a long period of time. Such a patient may believe that the non-conforming, generic equivalent is different, that it is a mistake in his/her prescription, or that it is less efficacious. The study conducted by Parke-Davis specifically found that colors are associated with the physiological effects of the drugs.

The district court summarized the evidence relating to the question of functionality and concluded that:

> "[M]any elderly patients associate the appearance of their medication with its therapeutic effect. . . . When patients associate the drug with

> its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage." (Pet.App. 63a)

The Second Circuit nevertheless labelled this evidence "unconvincing" and found that there was no evidence that the anxiety "could not easily be cured by explaining the change to the patient." This suggestion flatly contradicts Judge Nickerson's factual finding that:

> "There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors." (*Id.*)

It can thus be seen that if different colors must be used by generic manufacturers, a major effort will have to be made to overcome the patient's belief that there is something wrong with the drug. In addition, as noted above, even those efforts can never be completely successful, for many patients will never be convinced.

2. Confusion by Patients

As Judge Nickerson noted:

> "[S]ome patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. One doctor testified that he prepared a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs." (*Id.*)

This is particularly true for elderly persons who use multiple medications for daily use. Many patients place their daily pills in a carrying case, thereby comingling an assortment of drugs. The only source of identification would then be color, as, for example, in the "red heart pill." This conclusion is buttressed by the fact that many elderly citizens have impaired eyesight, obviating the value of any tiny imprinted marks.

3. Confusion as to Drug Identification

Another key functional aspect of color is its role in identification. As the Parke-Davis Study notes:

> "With more than 50,000 pharmaceutical specialties on the market, quick, accurate identification of one specific medication is of critical importance. . ."

The trial court made such a finding with respect to emergency situations. Hospital emergency rooms are often confronted with unidentified or partially-ingested drugs in an unconscious victim. Color is, as Parke-Davis notes, the most effective means for distinguishing among drugs:

> "An improvement in the safety of drugs is a matter of utmost urgency. . . .Fifty percent of the doctors questioned considered the risk of drug confusion to be great or very great. Eighty-four percent of the doctors thought that on account of this, drugs should be easier to identify by their appearance."
>
> * * *
>
> "The doctors were of the opinion that this could best be achieved by the use of color. That this

> opinion is a valid one is confirmed by an observation made on patients: when asked to say what they remembered about a medicine, practically all of them described it by its color."

Aids in identification are important in other hospital situations as well. Nurses administering a series of drugs to patients on a hospital floor usually put several drugs in each of numerous cups. The possibility for confusion is obviously great. Even imprinted identification numbers are of far less efficacy here than easy-to-identify colors. And where a single drug must be sold in several different colors the possibility of confusion is multiplied.

4. Psychological Effects of Color

In addition to other functional characteristics, color also speaks in psychological effects and motivations. Interestingly, that effect is reported by Parke-Davis, one of the brand-name companies:

> "A capsule which, through its color(s) conveys psychologically that it will be beneficial, builds patient confidence in the preparation. This leads to better patient compliance."

A similar finding as to color's psychological impact was reached in a recent article by the Director of the Institute for Biosocial Research.[4]

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4. Schauss, "Tranquilizing Effect of Color Reduces Aggressive Behavior and Potential Violence", 8 *J. Orthomolecular Psychiatry* 218 (1979).

Color is an essential element in the marketing of pharmaceutical products. Without equal access to the marketplace, generic pharmaceutical manufacturers are seriously hindered in their effort to bring lower-priced drugs to the public.

B. The Campaign Against Generic Drug Use

The drug industry has sales in excess of eight billion dollars annually. The large brand-name companies which control the industry charge 100%, 200% and, in some cases, even 400% more than do the generic manufacturers for the same products.

The propaganda for use of brand-name drugs is begun early in the physician's career. From his or her first year in medical school, the student receives free stethoscopes and other materials bearing these brand names. Huge promotional budgets underwrite student visits to the manufacturing plants. Once in practice, a doctor is deluged with prescription pads and other paraphernalia subliminally reinforcing use of the brand-name drug.

The influence of the huge multinational drug companies is enormous, and that influence extends into many spheres. Tremendous efforts have been made, for example, to frighten pharmacists and physicians through the use of "scare advertising," and to prevent the passage of pro-generic legislation. The object, once again, has been to thwart the sale of lower-priced, equivalent generic drugs.

This concerted effort by the large manufacturers did not accomplish its immediate objective, which was to stop passage of generic drug substitution laws. These companies, primarily through the Pharmaceutical Manufacturers Association ("PMA"), have spent millions of dollars in lobbying against a

panoply of measures which proposed to stimulate competition in the marketplace. Strong lobbying in numerous states was directed against legislation requiring posting of prescription drug prices in pharmacies, legislation requiring substitution of lower-priced drugs, regulations requiring a state to purchase generic drugs, and other measures which meant a lower cost to the public and to governmental purchasing agencies.

In conjunction with these efforts a misleading study was prepared. This study, sponsored by one PMA member, claimed significant differences in the quality of generic, as opposed to brand-name, drugs. The Commissioner of the FDA attacked the study, publicly pointing out that the conclusions were incorrect and that relevant data had been misused.

A spate of lawsuits then ensued in lock-step fashion. A number of the large companies brought "color lawsuits" against the same handful of generic manufacturers. These smaller manufacturers simply could not afford the defense costs of several protracted patent and trademark cases.

The "color cases" yielded conflicting and often one-sided results. As one legal commentator notes about decisions in this area:

> ". . . Something may be going on in these cases that is not reflected in the lines of the courts' published opinions. To predict these judgments is now simple, for the same side always wins. To understand the judgments, perhaps, use of a different discipline is required." Stern, "The Persantine, Librax & Elavil Decisions:

Colourful Brands of Drugs," 2 *Eur. Intel. Prop. Rev.* 59 (1981).[5]

More recently, some of the large PMA companies teamed up in a series of court actions in various parts of the country. At issue was the FDA's "paper NDA" policy, which facilitated the approval of generic drugs. As soon as one case was lost in the District of Columbia,[6] the same case was brought in Raleigh, North Carolina.[7] As soon as that case was lost, the same case was brought in Chicago.[8] That case lost as well. Although these efforts were not successful, a one-year delay was accomplished.

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5. Some decisions in England have recognized the need for the use of identically-colored capsules. *See, e.g., Roche Products Ltd. v. Berk Pharmaceuticals Ltd.*, [1973] RPC 473 (Supreme Court of Judicature); *Boots Co. Ltd. v. Approved Prescription Services, Ltd.*, [1980] ___ Ch. ___ B.No. 140 (Unreported: Martin Meredith) (Ch. Div. March 6, 1980), *aff'd*, [1980] B.No. 140 (Unreported: Association) (Court of Appeal Civ. Div. March 28, 1980).

6. *Hoffman-La Roche, Inc. v. Harris*, 484 F. Supp. 58 (D.D.C. 1979).

7. *Burroughs Wellcome Co. v. Schweiker*, 649 F. 2d 221 (4th Cir. 1981).

8. *American Critical Care, div. of American Hospital Supply Corp. v. Schweiker*, [CCH] Food, Drug, Cosmetic L. Rptr. ¶ 38,110 (N.D. Ill. May 13, 1981).

II.

THE DECISION BELOW IS CONTRARY TO THE IMPORTANT PUBLIC INTEREST IN LOWER-PRICED DRUGS AND EFFECTIVE COMPETITION IN THE PHARMACEUTICAL INDUSTRY

If the generic manufacturers can no longer comparatively advertise their products, and if they can no longer provide the color coding that the market demands, their ability to compete will have been seriously impaired. That has been the object of the large brand-name companies, and is the effect of the Second Circuit's decision.

The competing interests in this case can be easily delineated. The large brand-name companies assert an interest in the perpetual extension of their patent monopolies after the expiration of the seventeen-year protection. This translates into continued monopoly prices for those drug products.

The generic industry supports the public interest in lower-priced drugs and in the competitive presence of small businesses in this country. Pharmaceutical products are necessities, not luxuries, for a large part of the population (particularly the elderly). Fixed-income citizens are often forced to choose between exorbitantly-priced drugs and money for meals. One of the two must suffer. As Justice Blackmun said in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976):

> "Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs;

> yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. Where drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-764.

The importance of lower-cost pharmaceuticals extends to governmental purchasing bodies as well. Many state and federal agencies have turned to generic drugs and have recognized significant savings in the process.

In the past ten years, 49 states have enacted "substitution" laws.[9] These statutes reflect the fact that both public citizens

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9. Alabama Code, §34-23-8 (1979); Alaska Stat., §08.80.295 (1976); Arizona Rev. Stat. Ann., §32-1963.01 (1979); Arkansas Stat. Ann., §72-1047-1049 (1976); California (Business and Professions) Code, §§4047.6, 4047.7 (1976); Colorado Rev. Stat., §12-22-124 (1979); Connecticut Gen. Stat. Ann., §§20-185a through 20-185f (1976); Delaware Code Ann., Tit. 24, §2589 (1979); Florida Stat. Ann., §465.025 (1979); Georgia Code Ann., §§79A-408.1 through 79A-408.5 (1977); Hawaii Drug Product Selection Act, Hawaii Rev. Stat., Tit. 19, §§328-91 through 328-99 (1980); Idaho Ann., §§18-479-466, 17-479-460 in acc. with §37-2702(d) (1979) (supplement); Illinois Ann. Stat., ch. 111, §4033 (1977); Iowa Code Ann., §155.37 (1976); Kansas Stat. Ann., §65-1637 (1979); Kentucky Rev. Stat., §217.822 (1976); Louisiana Rev. Stat. Ann., §37-1225 (1979); Maine Rev. Stat. Ann., Tit. 32, §2806 (1975); Maryland (Health) Code Ann., §43-273A (1978); Massachusetts Ann. Laws, ch. 112, §12D (1976); Michigan M.C.L.A., §333.17755 (1978); Minnesota Stat. Ann., §151.21 (1975); Mississippi Code Ann., §§75-29-701 through 75-29-709 (1979); Missouri Drug Product Selection Law, Mo. Ann. Stat., §338.056 (1979); Montana Drug Product Selection Act, Mont. Rev. Codes Ann., §66-1528-66-1536 (1977); Nebraska Drug Product Selection Act, Neb. Rev. Stat., §§71-54.01 through 71-54.08 (1977) (1980 Supp.); Nevada Rev. Stat., §§639.2581 through 639.2599 (1979); New Hampshire Rev. Stat. Ann., ch. 146, §6-b (1973); New Jersey Stat.

(Cont'd)

and state agencies save a great deal of money when they purchase generic drugs.

Substitution laws either permit or require the substitution of lower-priced generic drugs for a brand-name product. In 11 states,[10] the statutes are "mandatory" in that the pharmacist must dispense the lower-priced drug unless the physician insists on having the brand-name product sold. The remaining states have "permissive" statutes, giving the pharmacist the option of dispensing the brand name or generic drug.

Substitution laws stand for recognition of the fact that: (a) generic drugs are therapeutically equivalent to the brand-name products; (b) generic drugs are almost always less costly; and (c) the public interest is best served by legislating substitution.

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Ann., §§24:6E-6 and 24:6E-7 (1977); New Mexico Stat. Ann., §26-3-3 (1976); New York, ch. 776, Laws of 1977 Reg. Sess.; North Carolina Gen. Stat., §90-76.1-76.6 (1980 Supp.); North Dakota Cent. Code, §19.02.1 - 14.1 (1979); Ohio Rev. Code Ann., §4729.38 (1978); Oklahoma, Tit. 59, §353.21 (1961); Oregon Rev. Stat., §689.515 (1979); Pennsylvania Stat. Ann., Tit. 35, §§960.1 - 960.7 (1976); Rhode Island, Gen. Laws, §5-19-38 (1976); South Carolina Drug Product Selection Act of 1978, Code §§39-24-10 through 39-24-40; South Dakota - Codified Laws Ann., §§36-11-46.1 through 36-11-46.4 (1978); Tennessee - Substitution of Equivalent Drug Product Act, Tenn. Code Ann., §39-2201 (1977); Texas [Health] Code Ann., Tit. 4542a, §12 (1978); Utah - Generic Substitution Act, Utah Code Ann., §§58-17-29 through 58-17-35 (1977); Vermont Stat. Ann., Tit, 18, §4605 (1977); Virginia Code, Tit. 32.1, §§79-87 (1976); Washington Rev. Code Ann., §§69.41.100 through 69.41.180 (1977); West Virginia Code §30-5-12b (1978); Wisconsin Stat. Ann., §140.90 (1976); Wyoming Generic Drug Substitution Act, Wyo. Stat., §§33-24-146 through 33-24-151 (1979).

10. Florida, Kentucky, Massachusetts, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington and West Virginia.

A detailed study of the effect of drug substitution laws was recently conducted by the University of Illinois. The conclusion was that:

> ". . . significant cost savings accrued to consumers when [drug substitution] occurred." Grussing, Purohit, Stewart. "Drug Product Selection in Illinois: An Evaluation of PA 80-976 After One Year of Experience." Summary of Major Findings at 2 (May 30, 1980).

The Illinois study of six other states[11] revealed that significant cost savings resulted in each state when generic drug substitution occurred. *Id.* at 87. The savings ranged from a low of $.86 to a high of $1.92 for each prescription. In 1980, more than 126 million prescriptions were filled in the United States. "The Top 200 Prescription Drugs of 1980", 183 *American Druggist*, 49, 52 (Feb. 1981). The use of generic drugs affords consumers of the nation potential savings of tens of millions of dollars per year.[12]

These substantial savings are jeopardized by the ill-founded decision of the Second Circuit. As Judge Nickerson noted:

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11. Michigan, Wisconsin, Florida, Vermont, Rhode Island and Delaware.

12. On April 10, 1981, the Department of Health for the State of New Jersey announced that its two-year generic drug law saved consumers $6 million. On March 3, 1981, the New Hampshire Council of Aging stated that New Hampshire's then proposed drug substitution law could save the elderly $2 million a year. One month prior, on February 3, 1981, a statewide community organization announced that if Texas adopted a drug substitution law, consumers would save upwards of $30 million. Texas became the 49th state to adopt such a law on May 28, 1981. On June 8, 1981, the New York City Department of Consumer Affairs announced that consumers had paid $12 million unnecessarily for medications because doctors and pharmacists have disregarded the State's generic drug law.

> "[T]he policy expressed in the New York Education Law [is] to encourage legal substitution of lower-priced drugs . . . To require different capsule colors . . . would also severely inhibit legal substitution which the legislature deems to be in the public interest." (Pet.App. 69a)

Nor is there any public interest in granting these already huge companies a virtual monopoly once their products' patents expire. We respectfully submit that there is a sound reason for the seventeen-year limitation on patents. That reason is to prevent monopolies *in perpetuo*, while providing a meaningful incentive for research. Generic competition is healthy and important. It cannot exist without the right to market effectively, a right which the Second Circuit has removed.

III.

THE OPINION OF THE COURT OF APPEALS IS IN ERROR AS TO THE LAW AND THE FACTS

The issue before the Court of Appeals was a fundamental one for this industry. The trial court properly held that generic drug companies were permitted to utilize comparative advertising and identical color combinations in order to compete effectively. That decision was premised upon proof that color serves a valid functional purpose.

We respectfully submit that the opinion of the Second Circuit, which reversed the trial court's findings, contains numerous logical and factual inconsistencies. Examples are set forth below:

1. On the second appeal, the court reaffirmed that the original evidence introduced by Ives as to illegal substitution of cyclandelate would not be sufficient to hold petitioners liable as contributory trademark infringers. The court held, however, that the "additional evidence" showed that in some cases of lawful substitution, the trademark CYCLOSPASMOL was placed by a druggist on the dispensing container. Claiming that such labelling was "widespread", the Court of Appeals held petitioners liable as contributory infringers. The court inexplicably failed to address, however, the threshold question of whether the acts of the pharmacists constituted trademark infringement. The result is that petitioners were held liable for contributory trademark infringement without a judicial finding at any level that trademark infringement, as such, ever occurred.

2. Judge Mansfield acknowledges that contributory trademark infringement requires some intentional suggestion, even if by implication, that the infringer engage in the actions

complained of. The opinion finds implicit suggestion only in catalogs and price sheets which describe the appearance of petitioners' drug product and comparatively list the generic cyclandelate available with the brand-name CYCLOSPASMOL as a reference. The court reasoned that the use of such catalogs amounted to a suggestion to pharmacists that they take advantage of the opportunity to engage in "misconduct". The problem is that the manufacturer-petitioners do not distribute their products or catalogs to retail pharmacies (with a few exceptions). There was clearly no basis for holding these companies liable as contributory trademark infringers, even under the court's own reasoning.

3. The court held that the generic companies had suggested, at least by implication, that the druggist or pharmacist engage in mislabelling to their "economic advantage". This statement is inexplicable. The lower court had found that all but one of the pharmacists who had mislabelled while lawfully substituting had charged the lower generic price for this product. There was thus no economic advantage to the druggist.

4. While conceding that the earlier instances of illegal substitution had been found by Judge Friendly to be insufficient and not widespread, Judge Mansfield nevertheless claims that the generic drug companies should have known that a substantial number of druggists would illegally substitute the generic product in place of CYCLOSPASMOL and that in fact illegal substitution of CYCLOSPASMOL is widespread. This result was accomplished by the court's taking judicial notice of six indictments handed down in New York City *after* the trial had been completed. The six indicted pharmacists were alleged to have illegally substituted generic products in place of CYCLOSPASMOL (as well as other products). The court stated that it was expressing no opinion as to the guilt or innocence of the parties in question. Yet at the same time, the court took

notice of the indictments as supposed proof that illegal substitution was widespread. The argument simply does not follow.

5. Judge Mansfield recognized that the evidence of illegal substitution of generic cyclandelate for CYCLOSPASMOL was scanty. The opinion nonetheless states that "taking into consideration the normal reluctance of any druggist to admit illegal conduct, it was surprising that Ives was able to produce as many such instances as it did." (Pet.App. 81a) The evidence of illegal substitution which was produced had nothing to do with admissions of illegal conduct by pharmacists. Rather, Ives based its evidentiary submission upon extensive shoppings it conducted in which bogus prescriptions were presented to unsuspecting pharmacists in an attempt to uncover illegal conduct. Many of these pharmacists were previously known to Ives to have a tendency to engage in illegal acts of substitution. This evidence does not support Judge Mansfield's conclusion.

We respectfully submit that the trial court's findings were fully supported by the record. We further submit that the reversal of those findings works a serious and unwarranted hardship on both the generic drug industry and the public.

CONCLUSION

For the foregoing reasons, NAPM respectfully requests that the decision of the United States Court of Appeals be reversed.

Respectfully submitted,

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